BILISTICK: A low cost point-of-care for early diagnosis of hyperbilirubinemia in newborns

Reporting

Project Information

BILISTICK
Grant agreement ID: 710971

Project website

Funded under
H2020-EU.3.1.3.

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1 February 2016

End date
31 July 2016

Overall budget
€ 71,429

EU contribution
€ 50,000

Coordinated by
BILIMETRIX SRL
Italy

Periodic Reporting for period 1 - BILISTICK (BILISTICK: A low cost point-of-care for early diagnosis of hyperbilirubinemia in newborns)

Reporting period: 2016-02-01 to 2016-07-31

Summary of the context and overall objectives of the project

Severe neonatal jaundice affects at least 481,000 newborns annually, from which 114,000 die and more than 63,000 survive with neurological sequelae caused by kernicterus/Chronic Bilirubin Encephalopathy (CBE). CBE is largely preventable if severe hyperbilirubinemia is early identified and treated. Indeed, AAP Guidelines (adopted by EU) recommend bilirubin screening during the first two weeks of life. However, existing solutions for bilirubin determination are inaccessible for many medical
settings, especially in Low and Middle Income Countries (LMICs), been them expensive or not enough accurate. The aim of the project is to perform a feasibility study to evaluate the success of the business to lead to the international market Bilistick® System, a low-cost Point-of-Care for early diagnosis of hyperbilirubinemia. Bilistick® is the only low cost, minimally invasive, portable in vitro rapid POC diagnostic device for bilirubin assay.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

During the development of the project, Bilimetrix analysed the main aspects for feasibility study, such as: market potential; analysis of competitors; possible pricing systems and methods of distribution; description of products and production process; individuation of partners (manufacturers, suppliers, distributors); market access and sales projection. Furthermore, it has developed an IPR protection strategy for the system and the trademark “Bilistick®” was registered. A special focus was done on regulatory requirements needed: Bilimetrix obtained the CE mark for the Bilistick® products and company certification ISO 13485:2012. Based on outcomes of the analysis, a financial analysis evaluation was done (5-year planning horizon). From a financial point of view, the project presents promising projections and sustainability. The main indicators for financial sustainability such as net income statement, cash flow and other estimated financial/economic reports resulted positive, supporting the feasibility of the project. As part of marketing costs considered, it was considered the possibility to sell an average of 10 devices per year at the production cost to selected institutions, and to grant to hospitals and organizations in selected LMICs some devices.

Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)

Based on the outcomes obtained from the feasibility study, it was demonstrated the validity of the project from a market, production and financial point of view. Bilimetrix plans to continue the development of the project until the insertion of the Bilistick® products in the market.
Bilistick® System, useful where it is needed

Bilistick® System, in vitro rapid POC Bilirubin assay
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